101-629

Public Law 101-629
101st Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.

Nov. 28, 1990
[H.R. 3095]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Safe Medical Devices Act of 1990

Health care.
21 USC 301 note.

SECTION 1. SHORT TITLE AND REFERENCE TO ACT.

(a) SHORT TITLE.—This Act may be cited as the "Safe Medical Devices Act of 1990".

(b) REFERENCE.—Whenever in this Act (other than in section 19) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. USER REPORTS.

(a) REQUIREMENT.—Section 519 (21 U.S.C. 360i) is amended by redesignating subsection (b) as subsection (c) and by inserting after subsection (a) the following:

"User Reports

"(b)(1)(A) Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that there is a probability that a device has caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device. In the case of deaths, the Secretary may by regulation prescribe a shorter period for the reporting of such information.

"(B) Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that there is a probability that a device has caused or contributed to the serious illness of, or serious injury to, a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.

"(C) Each device user facility shall submit to the Secretary on a semi-annual basis a summary of the reports made under subparagraphs (A) and (B). Such summary shall be submitted on January 1 and July 1 of each year. The summary shall be in such form and contain such information from such reports as the Secretary may require and shall include—

"(i) sufficient information to identify the facility which made the reports for which the summary is submitted,

"(ii) in the case of any product which was the subject of a report, the product name, serial number, and model number,

49-139 O - 90 (629)

AE 2.110:

READEX FICHE best copy available

"(iii) the name and the address of the manufacturer of such device, and

"(iv) a brief description of the event reported to the manufacturer.

The Secretary may by regulation alter the frequency and timing of reports required by this subparagraph.

"(D) For purposes of subparagraphs (A), (B), and (C), a device user facility shall be treated as having received or otherwise become aware of information with respect to a device of that facility when medical personnel who are employed by or otherwise formally affiliated with the facility receive or otherwise become aware of information with respect to that device in the course of their duties.

"(2) The Secretary may not disclose the identity of a device user facility which makes a report under paragraph (1) except in connection with—

"(A) an action brought to enforce section 301(q),

"(B) a communication to a manufacturer of a device which is the subject of a report under paragraph (1), or

"(C) a disclosure required under subsection (a).

This paragraph does not prohibit the Secretary from disclosing the identity of a device user facility making a report under paragraph (1) or any information in such a report to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

"(3) No report made under paragraph (1) by—

"(A) a device user facility,

"(B) an individual who is employed by or otherwise formally affiliated with such a facility, or

"(C) a physician who is not required to make such a report, shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.

"(4) A report made under paragraph (1) does not affect any obligation of a manufacturer who receives the report to file a report as required under subsection (a).

"(5) For purposes of this subsection:

"(A) The term 'device user facility' means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office. The Secretary may by regulation include an outpatient diagnostic facility which is not a physician's office in such term.

"(B) The terms 'serious illness' and 'serious injury' mean illness or injury, respectively, that—

"(i) is life threatening,

"(ii) results in permanent impairment of a body function or permanent damage to a body structure, or

"(iii) necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.".

21 USC 360i note.

(b) REGULATIONS.—The Secretary of Health and Human Services shall promulgate regulations to implement section 519(b) of the Federal Food, Drug, and Cosmetic Act, as added by the amendment made by subsection (a) (including a definition of the summary required by paragraph (1)(C) of such section) not later than 12 months after the date of enactment of this Act. In promulgating the

regulations, the Secretary shall minimize the administrative burdens on device user facilities consistent with the need to assure adequate information.

(c) EFFECTIVE DATE.—Section 519(b) of the Federal Food, Drug, and Cosmetic Act, as added by the amendment made by subsection (a), shall take effect— 21 USC 360i note.

(1) upon the effective date of regulations promulgated under subsection (b), or

(2) upon the expiration of 12 months from the date of the enactment of this Act,

whichever occurs first.

(d) EDUCATION AND INFORMATION.—During the 18-month period beginning on the date of the enactment of this Act, the Secretary of Health and Human Services shall inform device user facilities (as defined in section 519(b)(5)(A) of the Federal Food, Drug, and Cosmetic Act) and manufacturers and distributors of devices respecting the requirements of section 519(b) of such Act. Additionally, the Secretary, to the extent practicable, shall provide persons subject to the requirements of such section assistance in the form of publications regarding such requirements. 21 USC 360i note.

(e) STUDY.—Not more than 36 months after the date of the enactment of this Act, the Comptroller General of the United States shall conduct a study of— 21 USC 360i note.

(1) the compliance by device user facilities (as defined in section 519(b)(5)(A) of the Federal Food, Drug, and Cosmetic Act) with the requirements of section 519(b) of such Act,

(2) the actions taken by the manufacturers of devices in response to reports made to them under such section,

(3) the cost effectiveness of such requirements and their implementation, and

(4) any recommendations for improvements to such requirements.

The Comptroller General shall complete the study and submit a report on the study not later than 45 months from the date of the enactment of this Act. The report shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate and to the Secretary of Health and Human Services.

(f) REPORT TO CONGRESS.—Not later than 36 months after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report that contains an evaluation of the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act. In preparing the report, the Secretary shall consult with individuals and organizations with an interest in health care and consumer issues. At a minimum, the report shall contain— 21 USC 360i note.

(1) an evaluation of the safety benefits of the requirements,

(2) an evaluation of the burdens placed on the Food and Drug Administration and on device user facilities by the requirements,

(3) an evaluation of the cost-effectiveness of the requirements, and

(4) recommendations for legislative reform.

SEC. 3. REPORTS.

(a) DISTRIBUTOR REPORTS.—

(1) Section 519(a) (21 U.S.C. 360i(a)) is amended by striking out "and" at the end of paragraph (4), by striking out the period at the end of paragraph (5) and inserting in lieu thereof "; and", and by adding after paragraph (5) the following:

"(6) shall require distributors who submit such reports to submit copies of the reports to the manufacturer of the device for which the report was made.".

Effective date.
21 USC 360i note.

(2) Section 519(a)(6), as added by the amendment made by paragraph (1), shall take effect upon the effective date of final regulations under subsection (c).

(b) CERTIFICATION, DEVICE TRACKING.—

(1) Section 519 (21 U.S.C. 360i), as amended by section 2, is amended by adding at the end the following:

"Certification

"(d) Each manufacturer, importer, and distributor required to make reports under subsection (a) shall submit to the Secretary annually a statement certifying that—

"(1) the manufacturer, importer, or distributor did file a certain number of such reports, or

"(2) the manufacturer, importer, or distributor did not file any report under subsection (a).

"Device Tracking

"(e) Every person who registers under section 510 and is engaged in the manufacture of—

"(1) a device the failure of which would be reasonably likely to have serious adverse health consequences and which is (A) a permanently implantable device, or (B) a life sustaining or life supporting device used outside a device user facility, or

"(2) any other device which the Secretary may designate, shall adopt a method of device tracking.".

(2) Section 520(j) (21 U.S.C. 360j(j)) is amended by striking out "No" and inserting in lieu thereof "Except as provided in section 519(e), no".

21 USC 360i note.

(3) Section 519(e), as added by the amendment made by paragraph (1), shall take effect upon the effective date of final regulations under subsection (c).

21 USC 360i note.

(c) REGULATIONS.—

(1)(A) Not later than 9 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue proposed regulations—

Records.

(i) to require distributors of devices to establish and maintain records and to make reports (including reports required by part 803 of title 21 of the Code of Federal Regulations) under section 519(a)(6) of the Federal Food, Drug, and Cosmetic Act, and

(ii) to implement section 519(e) of such Act.

The Secretary may exempt from regulations described in clause (i) classes of distributors of class I and class II devices from whom reports are not necessary for the protection of the public health.

(B) Regulations under subparagraph (A) shall—

(i) require appropriate methods for maintenance of records to ensure that patients who receive devices can be provided the notification required by such Act,

(ii) require that manufacturers adopt effective methods of tracking devices,

(iii) take into account the position of distributors in the device distribution process, and

(iv) include such other requirements as the Secretary deems necessary for the adoption of an effective user tracking program under section 519(e) of such Act.

(2) Not later than 18 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement sections 519(a)(6) and 519(e) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not promulgate such final regulations upon the expiration of such 18 months, the Congress finds that there is good cause for the proposed regulations to be considered as the final regulations without response to comment because the implementation of sections 519(a)(6) and 519(e) of such Act are essential to protect the health of patients who use such devices. Consequently, in such event, the proposed regulations issued under paragraph (1) shall become final regulations as of the expiration of such 18 months. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations.

Federal Register, publication.

SEC. 4. SUBSTANTIAL EQUIVALENCE; CLASSIFICATION REVISION.

(a) SUBSTANTIAL EQUIVALENCE.—Section 513(f) (21 U.S.C. 360c(f)) is amended by adding at the end the following:

"(3) If a manufacturer reports to the Secretary under section 510(k) that a device is substantially equivalent to another device—

"(i) which the Secretary has classified as a class III device under subsection (b),

"(ii) which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and

"(iii) for which no final regulation requiring premarket approval has been promulgated under section 515(b),

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 510(k) a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the 510(k) report is being made and which has not been submitted to the Secretary under section 519. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.".

(b) REVISION OF CLASSIFICATION.—

(1) Section 515 (21 U.S.C. 360e) is amended by adding at the end the following:

"Revision

"(i)(1) Before December 1, 1995, the Secretary shall by order require manufacturers of devices, which were introduced or delivered for introduction into interstate commerce for commercial dis-

tribution before May 28, 1976, and which are subject to revision of classification under paragraph (2), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturer respecting such devices, including adverse safety or effectiveness information which has not been submitted under section 519. The Secretary may require the manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

Regulations. Federal Register, publication.

"(2) After the issuance of an order under paragraph (1) but before December 1, 1995, the Secretary shall publish a regulation in the Federal Register for each device—

"(A) which the Secretary has classified as a class III device, and

"(B) for which no final regulation has been promulgated under section 515(b),

revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a). Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this paragraph and provide reasonable opportunity for the submission of comments on any such regulation. No regulation requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of its publication in the Federal Register as a proposed regulation.

Regulations.

"(3) The Secretary shall, as promptly as is reasonably achievable, but not later than 12 months after the effective date of the regulation requiring a device to remain in class III, establish a schedule for the promulgation of a section 515(b) regulation for each device which is subject to the regulation requiring the device to remain in class III.".

(2) Section 520(l) (21 U.S.C. 360j(l)) is amended by adding at the end the following:

"(5)(A) Before December 1, 1991, the Secretary shall by order require manufacturers of devices described in paragraph (1), which are subject to revision of classification under subparagraph (B), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturers respecting the devices, including adverse safety or effectiveness information which has not been submitted under section 519. The Secretary may require a manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

Regulations. Federal Register, publication.

"(B) Except as provided in subparagraph (C), after the issuance of an order under subparagraph (A) but before December 1, 1992, the Secretary shall publish a regulation in the Federal Register for each device which is classified in class III under paragraph (1) revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a). Before the publication of a regulation requiring a device to remain in class III or

Regulations.

revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this subparagraph and provide an opportunity for the submission of comments on any such regulation. No regulation under this subparagraph requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of the publication in the Federal Register of the proposed regulation.

"(C) The Secretary may by notice published in the Federal Register extend the period prescribed by subparagraph (B) for a device for an additional period not to exceed 1 year.".

21 USC 360c note.

(3)(A) Notwithstanding section 520(l)(5) of the Federal Food, Drug, and Cosmetic Act, the Secretary of Health and Human Services shall not retain any daily wear soft or daily wear nonhydrophilic plastic contact lens in class III under such Act unless the Secretary finds that it meets the criteria set forth in section 513(a)(1)(C) of such Act. The finding and the grounds for the finding shall be published in the Federal Register. For any such lens, the Secretary shall make the determination respecting reclassification required in section 520(l)(5)(B) of such Act within 24 months of the date of the enactment of this paragraph.

Federal Register, publication.

(B) The Secretary of Health and Human Services may by notice published in the Federal Register extend the two-year period prescribed by subparagraph (A) for a lens for an additional period not to exceed one year.

(C)(i) Before classifying a lens in class II pursuant to subparagraph (A), the Secretary of Health and Human Services shall pursuant to section 513(a)(1)(B) of such Act assure that appropriate regulatory safeguards are in effect which provide reasonable assurance of the safety and effectiveness of such lens, including clinical and preclinical data if deemed necessary by the Secretary.

(ii) Prior to classifying a lens in class I pursuant to subparagraph (A), the Secretary shall assure that appropriate regulatory safeguards are in effect which provide reasonable assurance of the safety and effectiveness of such lens, including clinical and preclinical data if deemed necessary by the Secretary.

(D) Notwithstanding section 520(l)(5) of such Act, if the Secretary of Health and Human Services has not made the finding and published the finding required by subparagraph (A) within 36 months of the date of the enactment of this subparagraph, the Secretary shall issue an order placing the lens in class II.

(E) Any person adversely affected by a final regulation under this paragraph revising the classification of a lens may challenge the revision of the classification of such lens only by filing a petition under section 513(e) for a classification change.

SEC. 5. CLASSIFICATION AND RECLASSIFICATION OF DEVICES.

(a) STANDARDS.—

(1) Section 513(a)(1)(A)(ii) (21 U.S.C. 360c(a)(1)(A)(ii)) is amended by striking out "or to establish a performance standard" and inserting in lieu thereof "or to establish special controls".

(2) Section 513(a)(1)(B) (21 U.S.C. 360c(a)(1)(B)) is amended to read as follows:

"(B) CLASS II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.".

(3) Clause (i) of section 513(a)(1)(C) (21 U.S.C. 360c(a)(1)(C)) is amended to read as follows:

"(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and".

(b) CLASSIFICATION CHANGE.—Section 513(e) (21 U.S.C. 360c(e)) is amended by redesignating clauses (1) and (2) as clauses (A) and (B), respectively, and by inserting "(1)" after "(e)" and by adding at the end the following:

"(2) By regulation promulgated under paragraph (1), the Secretary may change the classification of a device from class III—

"(A) to class II if the Secretary determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device, or

"(B) to class I if the Secretary determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.".

(c) F.D.A. AUTHORITY TO INITIATE RECLASSIFICATION.—

(1) Section 513(f)(2)(A) (21 U.S.C. 360c(f)(2)(A)) is amended by striking out "The manufacturer" and inserting in lieu thereof "The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer".

(2) Section 520(l)(2) (21 U.S.C. 360j(l)(2)) is amended by striking out "The manufacturer" and inserting in lieu thereof "The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer".

(3) The heading for section 513(f) (21 U.S.C. 360c(f)) is amended by inserting "and Reclassification" before "of".

SEC. 6. ESTABLISHMENT OF PERFORMANCE STANDARDS.

(a) PROCEDURE.—Section 514 (21 U.S.C. 360d) is amended—

(1) in subsection (a), by amending the first sentence to read as follows: "The special controls required by section 513(a)(1)(B) shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device.",

(2) by striking out subsections (b) through (f),

(3) by redesignating subsection (g) as subsection (b),

(4) in subsection (b) (as redesignated), by amending paragraphs (1) and (2) to read as follows:

"(1)(A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device. Federal Register, publication.

"(B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall—

"(i) set forth a finding with supporting justification that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device,

"(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate,

"(iii) invite interested persons to submit to the Secretary, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to section 513(e) based on new information relevant to the classification, and

"(iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary.

"(C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

"(D) The Secretary shall provide for a comment period of not less than 60 days.

"(2) If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, after consultation with the appropriate panel under section 513, either deny the request or give notice of an intent to initiate such change under section 513(e).".

(b) CONFORMING AMENDMENTS.—

(1) Section 514(b) (as redesignated by subsection (a)(3)) is amended—

(A) in paragraph (3)(A), by striking out "paragraph (2)" and inserting in lieu thereof "paragraph (1)", and

(B) in paragraph (4)(A), by striking out "paragraphs (2) and (3)(B)" and inserting in lieu thereof "paragraphs (1), (2), and (3)(B)".

(2) Section 520(i) (21 U.S.C. 360j(i)) is amended by striking out "514(g)(5)(B)" and inserting in lieu thereof "514(b)(5)(B)".

SEC. 7. REPORTS OF REMOVALS AND CORRECTIONS.

Section 519 (21 U.S.C. 360i), as amended by sections 2 and 3, is amended by adding at the end the following:

"Reports of Removals and Corrections

"(f)(1) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer, importer, or distributor of a device to report promptly to the Secretary any correction or removal of a device undertaken by such manufacturer, importer, or distributor if the removal or correction was undertaken—

"(A) to reduce a risk to health posed by the device, or

"(B) to remedy a violation of this Act caused by the device which may present a risk to health.

A manufacturer, importer, or distributor of a device who undertakes a correction or removal of a device which is not required to be reported under this paragraph shall keep a record of such correction or removal.

"(2) No report of the corrective action or removal of a device may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

"(3) For purposes of paragraphs (1) and (2), the terms 'correction' and 'removal' do not include routine servicing.".

SEC. 8. RECALL AUTHORITY.

Section 518 (21 U.S.C. 360h) is amended by adding at the end the following new subsection:

"Recall Authority

"(e)(1) If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device)—

"(A) to immediately cease distribution of such device, and

"(B) to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device.

The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such device. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(2)(A) If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the device with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the device recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

Reports.

"(B) An amended order under subparagraph (A)—

"(i) shall—

"(I) not include recall of a device from individuals, and

"(II) not include recall of a device from device user facilities if the Secretary determines that the risk of recalling such device from the facilities presents a greater health risk than the health risk of not recalling the device from use, and

"(ii) shall provide for notice to individuals subject to the risks associated with the use of such device.

In providing the notice required by clause (ii), the Secretary may use the assistance of health professionals who prescribed or used such a device for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 705(b).

"(3) The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c).".

SEC. 9. TEMPORARY SUSPENSION OF APPROVAL OF APPLICATION.

(a) SUSPENSION.—Section 515(e) (21 U.S.C. 360e(e)) is amended—

(1) by adding at the end the following:

"(3) If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.", and

(2) in the subsection heading, by inserting "and Temporary Suspension" after "Withdrawal".

(b) CONFORMING AMENDMENT.—Section 501(f) (21 U.S.C. 351(f) is amended—

(1) in subparagraph (A)(ii)(II), by striking out "or withdrawn" and inserting in lieu thereof ", suspended, or withdrawn",

(2) in subparagraph (B)(ii), by striking out "which does not have such an application in effect" and inserting in lieu thereof "which has an application which has been suspended or is otherwise not in effect", and

(3) in subparagraph (C), by striking out "which does not have such an application in effect" and inserting in lieu thereof "which has an application which has been suspended or is otherwise not in effect".

SEC. 10. POSTMARKET SURVEILLANCE.

Subchapter A of chapter 5 is amended by inserting after section 521 (21 U.S.C. 360k) the following new section:

"POSTMARKET SURVEILLANCE

"SEC. 522. (a) IN GENERAL.— 21 USC 360*l*.

"(1) REQUIRED SURVEILLANCE.—The Secretary shall require a manufacturer to conduct postmarket surveillance for any device of the manufacturer first introduced or delivered for introduction into interstate commerce after January 1, 1991, that—

"(A) is a permanent implant the failure of which may cause serious, adverse health consequences or death,

"(B) is intended for a use in supporting or sustaining human life, or

"(C) potentially presents a serious risk to human health.

"(2) DISCRETIONARY SURVEILLANCE.—The Secretary may require a manufacturer to conduct postmarket surveillance for a device of the manufacturer if the Secretary determines that postmarket surveillance of the device is necessary to protect the public health or to provide safety or effectiveness data for the device.

"(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device under subsection (a) shall, within 30 days of the first introduction or delivery for introduction of such device into interstate commerce submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of useful data or other information necessary to protect the public health and to provide safety and effectiveness information for the device. The Secretary may not approve such a protocol until it has been reviewed by an appropriately qualified scientific and technical review committee established by the Secretary.".

SEC. 11. USE OF PREMARKET APPROVAL DATA.

Section 520 (21 U.S.C. 360j) is amended—

(1) in subsection (c)—

(A) by striking out "under section 513 from class III to class II" and inserting in lieu thereof "from class III to class II or class I", and

(B) by inserting "(1) in accordance with subsection (h), and (2)" after "except", and

(2) in subsection (h)—

(A) in paragraph (3), by striking out "Any" and inserting in lieu thereof "Except as provided in paragraph (4), any", and

(B) by adding at the end the following new paragraph:

"(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c), including clinical and preclinical tests or studies, but excluding descriptions of methods of manufacture and product composition, that demonstrates the safety and effectiveness of a device shall be available 1 year after the original application for the fourth device of a kind has been approved by the Secretary, for use by the Secretary in approving devices, or determining whether a product development protocol has been completed, under section 515, establishing a performance standard under section 514, and reclassifying devices under subsections (e) and (f) of section 513, and subsection (l)(2). The Secretary shall deem devices that incorporate the same technologies, have the same principles of operation, and are intended for the same use or uses to be within a kind of device.

Federal Register, publication.

"(B) The Secretary, contemporaneously with the approval of the fourth device of a kind, shall publish an order in the Federal Register identifying the four devices of a kind that have been approved under section 515 and the date on which the data contained in premarket approval applications for the devices will be available to the Secretary for use, as described in subparagraph (A).

"(C) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by para-

graph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the regulatory action described in subparagraph (A).

"(D)(i) This paragraph shall become effective— Effective date.

"(I) on November 15, 1990, for devices for which four devices of a kind were approved on or before December 31, 1987, and

"(II) on November 15, 1991, for devices not described in subclause (I).

"(ii) For each device described in clause (i)(I), the Secretary shall publish a notice in the Federal Register setting forth the date, which shall be not earlier than 1 year after the date of the notice, that data identified in subparagraph (A) shall be available for the use of the Secretary. Federal Register, publication.

"(E)(i) Except as provided in clause (ii), the approval date of a device, for purposes of this paragraph, shall be the date of the letter of the Secretary to the applicant approving a device under section 515 and permitting the applicant to commercially distribute the device.

"(ii) For each device described in subparagraph (D)(i)(II) for which the original application for a fourth device of a kind is approved by the Secretary before November 1, 1991, the approval date of the fourth device of a kind shall be deemed to be November 15, 1991.

"(F) Any challenge to an order under subparagraph (B) shall be made not later than 30 days after the date of the Federal Register notice referred to in such subparagraph.".

SEC. 12. SUBSTANTIAL EQUIVALENCE.

(a) SUBSTANTIAL EQUIVALENCE.—Section 513 (21 U.S.C. 360j) is amended by adding at the end the following new subsection: 21 USC 360c.

"Substantial Equivalence

"(i)(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term 'substantially equivalent' or 'substantial equivalence' means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

"(i) has the same technological characteristics as the predicate device, or

"(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

"(B) For purposes of subparagraph (A), the term 'different technological characteristics' means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

"(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

"(3)(A) As part of a submission under section 510(k) respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

Public information.

"(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.".

21 USC 360c note.

(b) REGULATIONS.—Within 12 months of the date of the enactment of this Act, the Secretary of Health and Human Services shall issue regulations establishing the requirements of the summaries under section 513(i)(3) of the Federal Food, Drug, and Cosmetic Act, as added by the amendment made by subsection (a).

SEC. 13. JUDICIAL REVIEW.

Section 517(a) (21 U.S.C. 360g(a)) is amended—

(1) by striking out "or" at the end of paragraph (6), and

(2) by inserting after paragraph (7) the following new paragraphs:

"(8) an order pursuant to section 513(i),

"(9) a regulation under section 515(i)(2) or 520(l)(5)(B), or

"(10) an order under section 520(c)(4)(B),".

SEC. 14. HUMANITARIAN DEVICE EXEMPTION.

(a) EXEMPTION.—Section 520 (21 U.S.C. 360j) is amended by adding at the end the following:

"Humanitarian Device Exemption

"(m)(1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States.

"(2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 514 and 515 for a device for which the Secretary finds that—

"(A) the device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States,

"(B) the device would not be available to a person with a disease or condition referred to in subparagraph (A) unless the Secretary grants such an exemption and there is no comparable device, other than under this exemption, available to treat or diagnose such disease or condition, and

"(C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

"(3) No person granted an exemption under paragraph (2) with respect to a device may sell the device for an amount that exceeds

the costs of research and development, fabrication, and distribution of the device.

"(4) Devices granted an exemption under paragraph (2) may only be used—

"(A) in facilities that have established, in accordance with regulations of the Secretary, a local institutional review committee to supervise clinical testing of devices in the facilities, and

"(B) if, before the use of a device, an institutional review committee approves the use in the treatment or diagnosis of a disease or condition referred to in paragraph (2)(A).

"(5) An exemption under paragraph (2) shall be for a term of 18 months and may only be initially granted in the 5-year period beginning on the date regulations under paragraph (6) take effect. The Secretary may extend such an exemption for a period of 18 months if the Secretary is able to make the findings set forth in paragraph (2) and if the applicant supplies information demonstrating compliance with paragraph (3). An exemption may be extended more than once and may be extended after the expiration of such 5-year period.

"(6) Within one year of the date of the enactment of this subsection, the Secretary shall issue regulations to implement this subsection.". Regulations.

(b) EFFECTIVE DATE.—Subsection (m) of section 520 of the Federal Food, Drug, and Cosmetic Act, as added by the amendment made by subsection (a), shall take effect on the effective date of the regulations issued by the Secretary under paragraph (6) of such subsection. 21 USC 360j note.

(c) REPORT.—Within 4 years after the issuance of regulations under section 520(m)(6) of the Federal Food, Drug, and Cosmetic Act, as added by the amendment made by subsection (a), the Secretary of Health and Human Services shall report to the Congress (1) on the types of devices exempted under such section, (2) an evaluation of the effects of such section, and (3) a recommendation on extension of the section. 21 USC 360j note.

SEC. 15. ESTABLISHMENT OF THE OFFICE OF INTERNATIONAL RELATIONS.

(a) OFFICE.—Title VIII is amended by adding at the end the following:

"OFFICE OF INTERNATIONAL RELATIONS

"SEC. 803. (a) There is established in the Department of Health and Human Services an Office of International Relations. 21 USC 383.

"(b) In carrying out the functions of the office under subsection (a), the Secretary may enter into agreements with foreign countries to facilitate commerce in devices between the United States and such countries consistent with the requirements of this Act. In such agreements, the Secretary shall encourage the mutual recognition of—

"(1) good manufacturing practice regulations promulgated under section 520(f), and

"(2) other regulations and testing protocols as the Secretary determines to be appropriate."

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a 21 USC 383 note.

report on the activities of the Office of International Relations under section 803 of the Federal Food, Drug, and Cosmetic Act, added by subsection (a).

SEC. 16. REVIEW OF MARKET APPLICATIONS FOR ARTICLES COMPRISING COMBINATIONS OF DRUGS, DEVICES, AND BIOLOGICS.

(a) REVIEW.—Section 503 (21 U.S.C. 353) is amended—

(1) by striking out the section heading and inserting in lieu thereof the following:

"EXEMPTIONS AND CONSIDERATION FOR CERTAIN DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS",

and

(2) by adding at the end the following:

"(f)(1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

"(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

"(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or

"(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

"(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

Regulations.

"(3) The Secretary shall promulgate regulations to implement market approval procedures in accordance with paragraphs (1) and (2) not later than 1 year after the date of enactment of this subsection.

"(4) As used in this subsection:

"(A) The term 'biological product' has the meaning given the term in section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

"(B) The term 'market clearance' includes—

"(i) approval of an application under section 505, 507, 515, or 520(g),

"(ii) a finding of substantial equivalence under this subchapter, and

"(iii) approval of a product or establishment license under subsection (a) or (d) of section 351 of the Public Health Service Act (42 U.S.C. 262).".

(b) DEFINITIONS.—Section 201 (21 U.S.C. 321) is amended—

(1) in paragraph (g)(1), by striking out "; but does not include devices or their components, parts, or accessories", and

(2) in paragraph (h)(3), by striking out "any of its principal" and inserting in lieu thereof "its primary".

SEC. 17. CIVIL PENALTIES.

(a) AMENDMENT.—Section 303 (21 U.S.C. 333) is amended by adding at the end the following:

"(f)(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this Act which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

"(B) Subparagraph (A) shall not apply—

"(i) to any person who violates the requirements of section 519(a) or 520(f) unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

"(ii) to any person who commits minor violations of section 519(e) or 519(f) (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

"(iii) to violations of section 501(a)(2)(A) which involve one or more devices which are not defective.

"(2)(A) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

"(B) In determining the amount of a civil penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

"(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

"(3) Any person who requested, in accordance with paragraph (2)(A), a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued.

"(4) If any person fails to pay an assessment of a civil penalty—

"(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (3), or

"(B) after a court in an action brought under paragraph (3) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (3) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action,

the validity, amount, and appropriateness of such penalty shall not be subject to review.".

Reports.
21 USC 333 note.

(b) EFFECTIVE DATE OF APPLICATION TO DEVICE USER FACILITIES.—

(1) The Secretary of Health and Human Services shall conduct a study to determine whether there has been substantial compliance with the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act by device user facilities (as defined in section 519(b)(5)(A) of such Act). The Secretary shall report the results of the study to the Congress after the expiration of 45 months after the date of the enactment of this Act.

(2)(A) If upon the expiration of 48 months after the date of the enactment of this Act the Secretary has not made the report required by paragraph (1), section 303(f) of the Federal Food, Drug, and Cosmetic Act, as added by the amendment made by subsection (a), shall take effect with respect to device user facilities (as defined in section 519(b)(5)(A) of such Act).

(B) If in the report under paragraph (1) the Secretary reports that there has been substantial compliance with the requirements of such section 519(b) by a type of device user facility and if the Secretary does not make a determination under subparagraph (C) with respect to such type of facility, such section 303(f) shall not take effect with respect to such type of facility.

(C) If the Secretary determines in the report under paragraph (1) that there is not substantial compliance with the requirements of such section 519(b) by a type of device user facility or if the Secretary makes such a determination after making the report under paragraph (1), such section 303(f) shall take effect with respect to such type of facility upon the effective date of the report.

SEC. 18. MISCELLANEOUS.

(a) SECTION 513(f).—Section 513(f)(2) (21 U.S.C. 360c(f)(2)) is amended in subparagraph (B)(i), by striking out "the Secretary shall" and inserting in lieu thereof "the Secretary may for good cause shown".

(b) SECTION 514.—Section 514(b) (21 U.S.C. 360d(b)(4)(B)) (as so redesignated) is amended—

(1) in paragraph (3)(B) (as so redesignated), by striking out ", after affording all interested persons an opportunity for an informal hearing,", and

(2) in clause (ii) of paragraph (4)(A) (as so redesignated), by striking out "unless" and all that follows in that clause and inserting in lieu thereof the following: "which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,".

(c) SECTION 515.—Section 515(c)(2) (21 U.S.C. 360e(c)(2)) is amended by striking out "paragraph (1), the Secretary shall refer such application" and inserting in lieu thereof "paragraph (1), the Secretary—

"(A) may on the Secretary's own initiative refer such application, or

"(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 513,

refer such application".

(d) SECTION 516.—Section 516(a) (21 U.S.C. 360f(a)) is amended (1) by striking out "and after consultation with the appropriate panel or panels under section 513", and (2) by striking out the last sentence.

(e) SECTION 520(f).—Section 520(f)(1)(A) (21 U.S.C. 360j(f)(1)(A)) is amended by inserting "pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device)," after "manufacture,".

(f) SECTION 520(l).—Section 520(l)(2) (21 U.S.C. 360j(l)(2)) is amended by striking out "and after affording the petitioner an opportunity for an informal hearing".

SEC. 19. ELECTRONIC PRODUCTS.

(a) IN GENERAL.—

(1) Subpart 3 of part F of title III of the Public Health Service Act is amended as follows: 42 USC prec. 263b.

(A) The heading for the subpart is amended to read as follows:

"SUBCHAPTER C—ELECTRONIC PRODUCT RADIATION CONTROL".

(B) The subpart is amended by striking out "subpart" each place it occurs and inserting in lieu thereof "subchapter". 42 USC 263b–263n.

(2)(A) Section 356 of such Act is amended— 42 USC 263d.

(i) by striking out "358" each place it occurs and inserting in lieu thereof "534", and

(ii) by striking out "sections 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5)" and inserting in lieu thereof "section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes of the United States (41 U.S.C. 5)".

(B) Section 358(a)(1)(E) of such Act is amended by striking out "355" and inserting in lieu thereof "531". 42 USC 263f.

(C) Section 359 of such Act is amended— 42 USC 263g.

(i) by striking out "358" each place it occurs and inserting in lieu thereof "534", and

(ii) by striking out "360A" each place it occurs and inserting in lieu thereof "537".

(D) Section 360 of such Act is amended by striking out "358" each place it occurs and inserting in lieu thereof "534". 42 USC 263h.

(E) Section 360A of such Act is amended— 42 USC 263i.

(i) by striking out "358" and inserting in lieu thereof "534", and

(ii) by striking out "359" each place it occurs and inserting in lieu thereof "535".

(F) Section 360B of such Act is amended— 42 USC 263j.

(i) by striking out "358" each place it occurs and inserting in lieu thereof "534",

(ii) by striking out "359" each place it occurs and inserting in lieu thereof "535", and

(iii) by striking out "360A" each place it occurs and inserting in lieu thereof "537".

(G) Section 360C of such Act is amended— 42 USC 263k.

(i) by striking out "358" and inserting in lieu thereof "534",

(ii) by striking out "360B" each place it occurs and inserting in lieu thereof "538", and

(iii) by striking out "360F" and inserting in lieu thereof "542".

42 USC 263n. (H) Section 360F of such Act is amended by striking out "358" and inserting in lieu thereof "534".

Repeal. 42 USC 263b. 42 USC 263c-263n. (3) Section 354 of such Act is repealed and sections 355 through 360F of such Act are redesignated as sections 531 through 542, respectively.

42 USC 263b-263n. (4) Subpart 3 of part F of title III of the Public Health Service Act, as amended by paragraphs (1) and (2) of this subsection, is transferred to chapter V of the Federal Food, Drug, and Cosmetic Act and is placed after section 528 and sections 354 through 360F of such subpart are redesignated as sections 530 through 542 of the Federal Food, Drug, and Cosmetic Act, respectively.

21 USC 360gg-360ss.

(b) CONFORMING AMENDMENT.—The heading for part F of title III of the Public Health Service Act is amended by striking out "AND CONTROL OF RADIATION".

42 USC prec. 262.

(c) CONSTRUCTION.—The transfer of subpart 3 of part F of title III of the Public Health Service Act to the Federal Food, Drug, and Cosmetic Act does not change the application of the requirements of such subpart and such Act to electronic products which were in effect on the date of the enactment of this Act.

21 USC 360hh.

Approved November 28, 1990.

LEGISLATIVE HISTORY—H.R. 3095 (S. 3006):

HOUSE REPORTS: No. 101-808 (Comm. on Energy and Commerce) and No. 101-959 (Comm. of Conference).

SENATE REPORTS: No. 101-513 accompanying S. 3006 (Comm. on Labor and Human Resources).

CONGRESSIONAL RECORD, Vol. 136 (1990):

Oct. 10, considered and passed House.

Oct. 12, H.R. 3095 considered and passed Senate, amended, in lieu of S. 3006.

Oct. 26, House agreed to conference report.

Oct. 27, Senate agreed to conference report.

○